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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,888	02/28/2002	Ephraim Carlebach	4026-4002US1	7721

7590 04/23/2003

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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

Office Action Summary	Application No.	Applicant(s)	
	10/085,888	CARLEBACH ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-28, 31, 33 and 35-43 is/are allowed.
- 6) ☒ Claim(s) 29, 30, 32, 34, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/590,202.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3,5</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 45 is objected to because of the following informalities: on line 9 of the claim "measurement.." should be replaced with "measurement.". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-30, 32, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 29, it is unclear whether the computational unit is part of the breath analyzer as claimed in claim 26 or whether it is separate. It is further unclear whether "the indication of the discrepancy" on line 6 of the claim is a separate indication from the indication provided by the breath analyzer in claim 26.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Rayburn et al. Rayburn describes a system comprising a differential pressure

flowmeter or pneumotachometer (15), a flow signal unit (14), a gas sensor (16), a CO₂ signal unit (13), a processor (12), and a data display (11). Expiratory signals from the CO₂ sensor (16) and pneumotachometer (15) are digitized and processed by the processor (12), which determines variables therefrom. Those variables are used to determine a value PaCO₂, where PaCO₂ is utilized to quantify pulmonary performance and/or determine the existence of lung failure or distress (fig. 1).

Allowable Subject Matter

Claims 29-30, 32, and 34 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 26-28, 31, 33, and 35-43 are allowed.

The following is an examiner's statement of reasons for allowance: Packer teaches a capnograph 10 connected via A/D converter 12 to computer 15. Mechanical ventilator 16 is also connected to converter 12 and computer 15. The PaCO₂ estimator 20 of the computer 15 determines the patient's arterial blood carbon dioxide partial pressure based upon a determination of a deadspace ratio (fig. 1). However, Packer lacks an analyzer that provides an indication of the discrepancy between the end tidal carbon dioxide partial pressure and the arterial carbon dioxide partial pressure of the subject.

Novotny et al. teaches a venous air embolism detector 10 including a respiratory gas analyzer 20, which receives and analyzes respiratory gases from a patient. The resulting carbon dioxide waveform 80 is sampled to determine the maximum carbon

dioxide concentration, which is determined to be the end-tidal carbon dioxide value (figs. 1 & 2). However, Novotny lacks an analyzer that provides an indication of the discrepancy between the end tidal carbon dioxide partial pressure and the arterial carbon dioxide partial pressure of the subject.

Therefore, no prior art exists teaching an apparatus for computerized breath analysis comprising a breath receiver in fluid communication with a subject and a breath analyzer, coupled to the receiver, that analyzes at least one breath of the subject and provides an indication of the discrepancy between the end tidal carbon dioxide partial pressure and the arterial carbon dioxide partial pressure in the subject, as claimed in claim 26.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Mon-Fri 9:30 am-7:00 pm (alternate Fri. off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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746-8117 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

pcm
April 15, 2003

Papina Mellai

Robert L. Nasser
ROBERT L. NASSER
PRIMARY EXAMINER